# Department of Health and Mental Hygiene

Larry J. Hogan, Jr. Governor - Boyd K. Rutherford, Lt. Governor - Van T. Mitchell, Secretary

#### MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue Baltimore, Maryland 21215-2299
Mitra Gavgani, Board President - Deena Speights-Napata, Executive Director

# VIA REGULAR & CERTIFIED MAIL, RETURN RECEIPT REQUESTED ARTICLE #7013 1090 0000 3937 7336

September 1, 2016

Rite Aid Pharmacy #104 238 McMechen Street Baltimore, MD 21217

Attn: Nancy Anyete-Anum, R.Ph.

Re:

Permit No. P00629, Case #PI-16-160

Notice of Deficiencies, Recommended Civil Monetary Penalty, and

Opportunity for Hearing

Dear Ms. Anyete-Anum:

On February 12, 2016, the Maryland Board of Pharmacy (the "Board") conducted an annual inspection of Rite Aid Pharmacy #104 (the "Pharmacy") for compliance with statutes and regulations governing the operation of a pharmacy. The Board's inspection and additional documentation indicated that the Pharmacy was not compliant with laws relating to pharmacy technician registration. Specifically, the Board inspector observed an unregistered pharmacy technician performing delegated pharmacy acts in the prescription area. The Pharmacy's training program documentation indicated that the technician completed a technician training program in July 2014. The Board's records indicate that the pharmacy technician submitted an application for registration on February 17, 2016, but a registration has not yet been issued.

#### I. FINDINGS AND CONCLUSION

The Board adopts as findings the deficiencies as stated in the Board's inspection report, dated February 12, 2016, and attached hereto as Exhibit A.

Based upon deficiencies at the Pharmacy, the Board finds that the Pharmacy is in violation of the Maryland Pharmacy Act; specifically, the Board finds the Pharmacy in violation of Health Occ. Art. §§ 12-403(c)(1) and 12-6B-01.

#### II. RECOMMENDED CIVIL MONETARY PENALTY

Under Maryland Health Occupations Article § 12-410 and COMAR 10.34.11, the Board of Pharmacy has the authority to impose a civil monetary penalty based upon violations of the Maryland Pharmacy Act.

Based upon the deficiencies cited at the Pharmacy, the Board hereby recommends the imposition of a **civil monetary penalty of \$1,000.00**. The deficiencies upon which the civil monetary penalty is based are set forth above in this Notice.

In determining the recommended civil monetary penalty, the Board took into consideration the aggregating and mitigating factors outlined in COMAR 10.34.11.08.

#### III. FOLLOW-UP INSPECTION

Please be advised that the Board of Pharmacy may perform a follow-up inspection of the Pharmacy to insure that the deficiencies noted herein have been addressed and corrected. Should the follow-up inspection indicate that the Pharmacy has further deficiencies, the Board may pursue further disciplinary action against the Pharmacy that may result in the imposition of sanctions such as suspension, revocation or additional monetary penalties.

### IV. OPPORTUNITY FOR HEARING

If the Pharmacy disputes the findings, conclusions or the civil monetary penalty, the Pharmacy may request an evidentiary hearing on the Board's decision in this matter. In the event that the Pharmacy requests an evidentiary hearing, the Board shall initiate formal proceedings which will include the opportunity for a full evidentiary hearing. The hearing will be held in accordance with the Administrative Procedure Act, Md. Code Ann. State Gov't § 10-201 et seq., and COMAR 10.34.01. Any request for a hearing must by submitted in writing to Vanessa Thomas Gray, Compliance Investigator, Maryland Board of Pharmacy, 4201 Patterson Ave., 5<sup>th</sup> Floor, Baltimore, Maryland 21215, **no later than thirty** (30) days of the date of this Notice.

Please be advised that at the hearing the Pharmacy would have the following rights: to be represented by counsel, to subpoena witnesses, to call witnesses on its own behalf, to present evidence, to cross-examine witnesses, to testify, and to present summation and argument. Should the Board find the Pharmacy guilty of the violations cited in the Reports,

the Board may suspend or revoke the pharmacy permit, or impose civil penalties, or both. If the Pharmacy requests a hearing but fail to appear, the Board may nevertheless hear and determine the matter in the Pharmacy's absence.

### V. OPTION TO PAY RECOMMENDED CIVIL MONETARY PENALTY

Alternatively, the Pharmacy may pay the recommended civil monetary penalty within thirty (30) days of the date of this Notice, in the form of a certified check or money order made payable to the Maryland Board of Pharmacy.

Please mail the check or money order to:

Maryland Board of Pharmacy P.O. Box 2051 Baltimore, MD 21203-2051

NOTE: Please include the case number, Pl-16-160, on your check or money order to insure proper assignment to your case.

Upon the Pharmacy's payment of the civil monetary penalty, this Notice will constitute the Board's final action with respect to the inspection report dated, February 12, 2016, and shall be a public document in accordance with the Maryland Public Information Act.

If you have any questions concerning the instructions contained in this letter, please contact Vanessa Thomas Gray, Compliance Investigator, at 410-764-2493.

Sincerely,

Déena Speights-Napata

**Executive Director** 

cc: Linda Bethman, Board Counsel
Deborah Hurley, Rite Aid Corporation

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Department of Health and Mental Hygiene

Lawrence J. Hogan, Jr., Governor - Boyd K. Rutherford, Lt. Governor Van T. Mitchell, Secretary

OF PHARMACY

Raltimore, Maryland -
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STATE OF MARYLAND



MARYLAND BOARD OF PHARMACY

4201 Patterson Avenue • Baltimore, Maryland 21215-2299 Mitra Gavgani, Board President - LaVerne G. Naesea, Executive Director

COMMUNITY PHARMACY INSPECTION FORM
Corporate Pharmacy Name Rite Aid of Maryland Inc.
Pharmacy Name-Doing Business as (d/b/a) or Trade Name Rite Aid Discount Pharmacy 104
Street Address 238 McMechen Street, Baltimore, Maryland 21217
Business Telephone Number 410-523-4704 Business Fax Number 410-523-6894
Inspection Date: 2/12/2016 Arrival Time: 2pm Departure Time: 4pm
Type of Inspection: Annual Follow-up Previous Date: 3/27/2016  Name of Inspector: Shanelle Young
Traine of mispector: Shahelle foung
1. GENERAL INFORMATION
Yes No The pharmacy hours of operation are prominently displayed if the prescription area is not
open the same hours as the establishment.  Pharmacy Hours M-F: Sam-Spm Sat: Sam-Spm Sun: 10am-Som
Priarmacy Hours M-F: Sam-Spm Sat: Sam-Spm Sun: 10am-Spm
Yes No All permits, licenses, and registrations are posted conspicuously. HO § 12-311, HO § 12-408(b) and HO § 12-6B-08
Maryland Pharmacy Permit Number P00629 Expiration Date: 5/31/2016
Maryland Pharmacy Permit Number P00629 Expiration Date: 5/31/2016 CDS Registration Number 411721 Expiration Date: 1/31/2017
DEA Registration Number AR8513740 Expiration Date: 6/30/2018
Yes No The pharmacy performs sterile compounding. (If yes, complete Sterile Compounding Inspection Form) COMAR 10.34.19
Yes No The pharmacy provides services to Comprehensive Care facilities or assisted living facilities. (If yes, complete Comprehensive Inspection Form) COMAR 10.34.23
Yes No The pharmacy fills original prescriptions received via the internet.
Yes No The pharmacy fills original prescriptions via e-prescribing.
Yes No The pharmacist fills mail order prescriptions.
If yes to any of the above, how does the pharmacist verify that a relationship exists between the patient and the prescriber? 21 C.F.R. § 1306.04, HG § 21-220; COMAR 10.19.03.02 and .07
Comments:
Per Shyam Abraham, the pharmacist calls to verify original prescriptions sent via e-prescribing if needed.

#### 2. PERSONNEL

Name of Pharmacist/Manager who is charged with ensuring compliance with all applicable laws Nancy Anyete-Anum

18234 23646 21940 Registration #	4/30/2016 10/2016 5/2017
Registration #	5/2017
Registration #	
T05114	Exp Date10/2016
T10041	5/2017
T11454	10/2017
Title Fechnician in Training	Duties
	T11454

3. PERSONNEL TRAININ	iG
Yes No N/A	There are written policies and procedures to specify duties that may be performed by unlicensed personnel under the supervision of a licensed pharmacist. COMAR 10.34.21.03 and 10.34.21.05
Yes No N/A	All unlicensed personnel who perform tasks in the pharmacy receive documented training for the tasks they perform. COMAR 10.34.21.03B(1)
All personnel have received tra	nining in: (check all that apply) COMAR 10.34.21.03B(3) and (4)
Yes 🗸 No 📗 N/A	Maintaining records
Yes ✓ No 🔲 N/A	Patient confidentiality
Yes ✓ No 🔲 N/A	Sanitation, hygiene, infection control
Yes 🗸 No 🔲 N/A	Biohazard precautions
Yes No N/A	Patient safety and medication errors COMAR 10.34.26.03
Comments:	A)
	ted on the intra net. See attached training documentation for tech in training.
Yes No The pharmacy w	wholesale distributes to another pharmacy (COMAR 10.34.37) wholesale distributes to a wholesale distributor (COMAR 10.34.37) The wholesale distribution business exceeds 5% of the pharmacy annual sales COMAR 10.34.37)
4. SECURITY COMAR 10.	34.05
closed di	is designed to prevent unauthorized entry when the prescription area is uring any period that the rest of the establishment is open. (If yes, briefly how access is restricted.) COMAR 10.34.05.02A (5)
Comments:	
Locked door, gates, cameras a	nd motion detection.
2	
Yes No The pharmac 10.34.05	y and/or pharmacy department has a security system. COMAR 02A (2)

Yes No The permit holder shall prevent an individual from being in the prescription area unless a pharmacist is immediately available on the premises to provide pharmacy services. COMAR 10.34.05.02A (3)
Comments:
None.
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5. PHYSICAL REQUIREMENTS AND EQUIPMENT
Yes No Pharmacy area is clean and orderly. HO 8 12-403(b) (11) (ii)2
1 1 105 (b) (11) (h)
Yes No The pharmacy provides a compounding service (non-sterile procedures).
Yes ✓ No If yes, the pharmacy maintains equipment that enables it to prepare and dispense prescriptions properly within its scope of practice. COMAR 10.34.07.02
Yes No The pharmacy has a Class A prescription balance and weights, or a prescription balance with equivalent or superior sensitivity. COMAR 10.34.07.01A
Yes ✓ No The pharmacy has hot an d cold running water.
Yes No The medication refrigerator(s) contain only prescription items. COMAR 10.34.07.01B
Yes No The medication refrigerator(s) have a thermometer and the current temperature is between (36-46F) USP. COMAR 10.34.07.01B
Temperature 37F
Yes No The current temperature of the pharmacy department is between 59 to 86 degrees F. COMAR 10.34.05.02A (1)(a)
Temperature 69F
Yes No N/A If the pharmacy stocks medications requiring freezing, the freezer is maintained at temperatures required by the medications stored within it.  Temperature -3F
Yes No The pharmacy maintains at all times a current reference library that is appropriate to meet the needs of the practice specialty of that pharmacy and the consumers the pharmacy serves. HO § 12-403(b)(10)
Yes / No The pharmacy has online resources. HO § 12-403(b)(15)
Comments:
None.

Yes ✓ No Prescription files for each prescription prepared or dispensed are made and kept on file for at least 5 years. HO § 12-403(b)(13)(i)
The following label requirements are met if a drug is dispensed pursuant to a prescription: HO § 12-505
Yes ✓ No
Comments:
Technician's initials can be identified in the computer system. See attached phormony label
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7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS
7. QUALITY ASSURANCE – PATIENT SAFETY / MEDICATION ERRORS  Yes No There are written policies that inform patients of the procedure to follow when reporting a suspected medication error to the permit holder, pharmacist, health care facility, or other health care povider. COMAR 10.34.26.02  Yes No The pharmacy maintains a minimum of two (2) continuous years of records clearly demonstrating the content of annual educational training provided to each member of the pharmacy staff involved in the medication delivery system regarding the roles and responsibilities of pharmacy staff in preventing medication errors.
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8. CONFIDENTIALTY
Yes No Confidentiality is maintained in the creation, storage, access disposal and disclosure of patient records. HO § 12-403(b)(13), COMAR 10.34.10.03A and HIPAA Regulations
Yes No Any identifiable information contained in a patient's record is not disclosed unless authorized by the patient, or an order of the court, or as authorized pursuant to HG §4-301 through §4-307. COMAR 10.34.10.03B
Comments:
None.
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9. INVENTORY CONTROL PROCEDURES
Yes No N/A The pharmacy maintains invoices as required by law for accurate control and accountability of all pharmaceuticals. COMAR10.34.24.03
Yes No N/A The pharmacy has a procedure in place for removal of all expired drugs (both prescription and OTC). COMAR 10.34.12.01
Yes No No N/A The pharmacy maintains records of wholesale distribution to other pharmacies separately from its other records. COMAR 10.34.37.03
Yes No N/A N/A The pharmacy maintains records of wholesale distribution to wholesale distributors separately from its records of wholesale distribution to other pharmacies. COMAR 10.34.37.03
Comments:
None.
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10. CONTROLLED SUBSTANCES
Power of Attorney Shyam Abraham & Ijeoma Agbara
Yes ✓ No The pharmacy has a record of the most recent required biennial inventory of Schedule II-V controlled substances. COMAR 10.19.03.05B
Inventory date: 5/1/2015
Biennial Inventory completed at Opening or Closing (circle one)
Yes ✓ No The inventories and records of Schedule II-V drugs are maintained and readily available.  COMAR 10.19.03.05 and 21 CFR 1304.03
Yes No Records are kept of all receipts of controlled substances entered into the pharmacy
inventory (including DEA Form 222 or CSOS orders). COMAR 10.19.03.05
Yes ✓ No There are written policies and records for return of CII, CIII-V.
Yes ✓ No Hard copy or electronic prescription files are maintained chronologically for 5 years.
Yes No Schedule II controlled substances are dispersed throughout the stock of non-controlled substances or stored in such a manner as to obstruct theft or diversion. COMAR 10.19.03.12B (2)

	rolled substances prescriptions bear the name and address of the prescriber and ient. COMAR 10.19.03.07D (1)
Yes No The perm	nit holder or pharmacist designee(s) has written policies and procedures for estigating discrepancies and reporting of theft or loss. COMAR 10.19.03.12B
Comments:	
Reviewed controlled retu	ms to Med-Turn.
11. AUTOMATED M	EDICATION SYSTEMS Yes No (if No, go to #12)
Yes No N/A ✓	The facility uses an automated device(s) as defined in COMAR 10.34.28.02.
Policies and proc	cedures exist for (check all that apply): COMAR 10,34,28.04A
Yes No No N/	A Operation of the system
Yes No N/	A Training of personnel using the system
Yes No No N/	A Operations during system downtime
Yes No No	Control of access to the device
Yes No N/	A Accounting for medication added and removed from the system.
Yes No N/A	Sufficient safeguards are in place to ensure accurate replenishment of the automat medication system. If yes, describe safe guards. COMAR 10.34.28.06
N/A	
Adequate records are ma	aintained for at least two years addressing the following (check all that apply).
Yes No N/A	Maintenance records.
Yes No N/A	System failure reports.
Yes No N/A	Accuracy audits.
Yes No N/A	Quality Assurance Reports.
Yes No N/A	and the second
Yes No N/A	jained .
Yes No N/A	Devices installed after September 1, 2003 operate in a manner to limit simultaneous access to multiple strengths, dosage forms, or drug entities, and minimize the potential for misidentification of medications, dosages, and dosage forms accessed from the automated medication system. COMAR 10.34.28.04B
Yes No N/A	The pharmacy has records, documents, or other evidence of a quality assurance program regarding the automated medication system in accordance with the requirements of COMAR 10.34.28
Comments:	
N/A	

12. OUTSOURCING	Yes No ✓ (if No, go to #13)
Yes No N/A	The facility outsources the preparation of medication or performs outsourcing functions for other pharmacies. COMAR 10.34.04.02
Yes No N/A	The facility serves as a primary pharmacy outsourcer to other pharmacies. COMAR 10.34.04.02
Yes No N/A ✓	The facility serves as a secondary pharmacy. COMAR 10.34.04.02
Yes No N/A	The permit holder employs an outside agency/business entity for the provision of any pharmacy services, inclusive of staffing, remote order entry, and management.
	If yes: Name of agency, state of incorporation, service contracted, and State of Maryland License/Permit Number: COMAR 10.34.04.06E
Comments: N/A	
Yes No N/A	The permit holder has written policies and procedures to specify the duties that may be performed by outside personnel. COMAR 10.34.21.03B(3)
If the pharmacy outsources	•
Yes No N/A	The original prescription order is filed as a prescription order at the primary pharmacy. COMAR 10.34.04.06D
Yes No N/A	Written policies exist for maintenance of documentation regarding transfer of prescription records. COMAR 10.34.04.06
Yes No N/A	Documentation is maintained, including the names and locations of the pharmacies, names of pharmacists, and a record of the preparations made.  COMAR 10.34.04.03 and .05
The pharmacist from the identifiable manner: COM	primary pharmacy documents the following in a readily retrievable and AR 10.34.04.06 (Check all that apply)
Yes No N/A ✓	That the prescription order was prepared by a secondary pharmacy.
Yes No N/A	The name of the secondary pharmacy.
Yes No N/A ✓	The name of the pharmacist who transmitted the prescription order to the secondary pharmacy.
Yes No N/A	The name of the pharmacist at the secondary pharmacy to whom the prescription order was transmitted if the transmission occurred in an oral manner.
Yes No N/A	The date on which the prescription order was transmitted to the secondary pharmacy.
Yes No N/A ✓	The date on which the medication was sent to the primary pharmacy.
Yes No N/A	The primary and secondary pharmacies are both licensed in the State of Maryland, or operated by the federal government. COMAR 10.34.04.06F
Yes No N/A	The primary pharmacy maintains, in a readily retrievable and identifiable manner, a record of preparations received from the secondary pharmacy. COMAR 10.34.04.06G

	t the secondary pharmacy maintains documentation in a readily retrievable and which includes: COMAR 10.34.04.07 (Check all that apply)
Yes No N/A	✓ That the prescription order was transmitted from another pharmacy.
Yes No N/A	The name and information identifying the specific location of the primary pharmacy.
Yes No N/A	The name of the pharmacist who transmitted the prescription to the secondary pharmacy if the transmission occurred in an oral manner.
Yes No N/A	The name of the pharmacist at the secondary pharmacy who accepted the transmitted prescription order.
Yes No N/A	The name of the pharmacist at the secondary pharmacy who prepared the prescription order.
Yes No N/A	The date on which the prescription order was received at the secondary pharmacy.
Yes No N/A	The date on which the prepared product was sent to the primary pharmacy if it was sent back to the primary pharmacy.
13. Recommended	Best Practices
Yes ✓ No A	perpetual inventory is maintained for Schedule II controlled substances.
Yes ✓ No T	here are documented contingency plans for continuing operations in an emergency and for disaster recovery of required records.
Yes ✓ No T	he pharmacy has written policies and procedures for the safe handling of drug recalls.  See www.recalls.gov
Yes ✓ No T	he pharmacy maintains records of all recalls. See www.recalls.gov
INSPECTOR'S CO	
	orm with Shyam Abraham, Staff Pharmacist. There were no discrepancies found during inventory. There were no outdated or mis-labeled items found during spot check of
	Policies/procedures, training and QA are on the pharmacy's intra net. There was 1
	n duty Ashley Reid. Per pharmacy manager, Ashley has completed her training and has sent
her technician registrat	ion application to the Board. Per Ashley, she has worked on and off in the pharmacy since
	an training program in 2014. See attached training documentation for Ashley.
	- W. WINDOWS - AND THE STATE OF
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<del>8-11-11-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1-1</del>	
Inspector Signatur	e Shandal Varing
Pharmacist Name	((Print): Shyam Abraham Date: 2/12/2016
Signature:	*
-	this inspection report:
	Date and Pharmaciet Staneture

FINAL 09/02/2014

# CONTROLLED DANGEROUS SUBSTANCES WORKSHEET

Date: 2/12/2016 Pharmacist Signature:	*	_
I normacist organitatio.	7	
Rx#: 07	779821	
Date F	illed: 2/12/2016	_
	12	
	NDC Number	ON HAND INVENTORY
ate CD 30mg	53014-0581-07	50
done 5mg	00406-5775-01	130
done 15mg	00229-2878-11	133
se 50mg	59417-0105-01	65
COMMENTS		
COMMENTS:		
No discrepancies.	STATE OF THE STATE	· · · · · · · · · · · · · · · · · · ·
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	SCHEDULE II AUDIT	
	SCHEDULE II AUDIT  Drug NA Date of last Inspection/Biennial NA	
Amount at last inspection/bien	Drug N/A Date of last Inspection/Biennial N/A	(A)
Amount at last inspection/bien Purchased since inspection/bie	Drug N/A Date of last Inspection/Biennial N/A	(A) (B)
Purchased since inspection/bie Total inventory	Drug N/A Date of last Inspection/Biennial N/A  nial ennial	(B) $(C) = A + B$
Purchased since inspection/bie Total inventory Quantity dispensed	Drug N/A Date of last Inspection/Biennial N/A  nial ennial	(B) (C) = A + B (D)
Purchased since inspection/bie Total inventory Quantity dispensed Expected inventory	Drug N/A Date of last Inspection/Biennial N/A mial ennial	(B) (C) = A + B (D) (E) = C - D
Purchased since inspection/bie Total inventory Quantity dispensed Expected inventory Quantity on Hand	Drug N/A Date of last Inspection/Biennial N/A mial ennial	(B) (C) = A + B (D) (E) = C - D (F)
Purchased since inspection/bie Total inventory Quantity dispensed Expected inventory	Drug N/A Date of last Inspection/Biennial N/A mial ennial	(B) (C) = A + B (D) (E) = C - D
Purchased since inspection/bie Total inventory Quantity dispensed Expected inventory Quantity on Hand	Drug N/A Date of last Inspection/Biennial N/A mial ennial	(B) (C) = A + B (D) (E) = C - D (F) (G) = (F-E) or (E-F)
Purchased since inspection/bie Total inventory Quantity dispensed Expected inventory Quantity on Hand Discrepancy	Drug N/A Date of last Inspection/Biennial N/A mial ennial 0	(B) (C) = A + B (D) (E) = C - D (F) (G) = (F-E) or (E-F)
Purchased since inspection/bie Total inventory Quantity dispensed Expected inventory Quantity on Hand Discrepancy  CII:	Drug N/A Date of last Inspection/Biennial N/A mial ennial 0	(B) (C) = A + B (D) (E) = C - D (F) (G) = (F-E) or (E-F)
Purchased since inspection/bie Total inventory Quantity dispensed Expected inventory Quantity on Hand Discrepancy	Drug N/A Date of last Inspection/Biennial N/A mial ennial 0	(B) (C) = A + B (D) (E) = C - D (F) (G) = (F-E) or (E-F)
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## PRESCRIPTION REVIEW

СП# 777790-779821 DATE 2/1-2/12/2016

OMMENTS:	CIII - CV # 779401-449499	
lone.		<b>DATE</b> 2/10-2/10/2016
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AID-238 MCMBCHBN ST (410) 523-4704	AID-238 MCMECHEN ST (410) 5 CMECHEN STREET MORE, MD 21217	V

VYVANSE 60 MG CAPSULE

OBLONG AQUA BLUB 60 mg
Libir SHIRE US INC
Pr. PAULINO-WOOLRIDGE, JOHANNA F
QTY: 30
DRGEXP 02/12/2017
NO REFILLS LEFT